K 073475

MAR 10 2008

Summary of Safety and Effectiveness

System Plus Impression Material

1. **Date of Summary Preparation:** June 22, 2007

2. **Submitting Firm:** Continental Dental Laboratory

3. **Contact Person:**

Jerry Doviack, CDT
President
Continental Dental Laboratory
1873 Western Way
Torrance, CA 90501
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4. **Name of Medical Device**

Proprietary Name: System Plus Impression Material

Common Name: Dental Impression Material

Classification Name: Impression Material

5. **Description of Medical Device:**

System Plus is an addition-reaction silicone impression material. This vinyl polysiloxane (VPS) impression material comes in two different viscosities intended to help reproduce the structure of a patient's teeth and gums in order to produce, crowns, bridges, implants, and other dental restorations.

Physical Properties

PROPERTY	MEDIUM BODY	LIGHT BODY
Consistency, ISO 4823	Medium Body, Type 2	Light Body, Type 3
Color	yellow	blue
Working Time (Including Mixing)	30 -60 seconds	30-60 seconds
Time in Mouth	three minutes	three minutes
Total Setting Time (Including Mixing)	four minutes	four minutes
Strain in Compression %	4.7%	4.7%
Shrinkage after 24hr	<0.1%	<0.1%
Shore A Hardness	45	45

6. **Intended Use**

This VPS impression material is intended to be placed on an impression tray and used to reproduce the structure of a patient's teeth and gums in order to produce crowns, bridges, implants and other dental restorations. This product is for professional use only by or on the order of a licensed dentist.

7. **Substantial Equivalence Determination**

Continental Dental Laboratory has determined that System Plus Impression Material is substantially equivalent to:

K052090, Splash! – Discus Dental, Inc.

Predicate Similarities

PRODUCT	COMPANY	ISO 4823	STRAIN IN COMPRESSION	SHRINKAGE	SHORE A HARDNESS
System Plus	Continental Dental Lab	Type 2-3	<5%	<.1%	45
Splash!	Discus Dental	Type 0-3	2.3-2.5%	<.1%	62-67

Predicate Differences

PRODUCT	COMPANY	WORKING TIME (INC MIXING)	TIME IN MOUTH	TOTAL SETTING TIME	SHORE A HARDNESS
System Plus	Continental Dental Lab	30-60 seconds	3 minutes	≤ 4 minutes	45
Splash!	Discus Dental	55-65 seconds	1 min 15 sec	2 min. 15 sec	62-67

8. **Safety & Effectiveness**

Continental Dental Laboratories acknowledges that when used as directed, there are no known harmful reactions or side effects on patients and/or dental personnel using vinyl polysiloxane impression materials.

The company will continue to conduct safety assessments based on further research and analysis to ensure compliance with safety and performance specifications recorded and published for this product.

END OF SECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kareen Chamberlain
Marketing Director
Continental Dental Laboratory
1873 Western Way
Torrance, California 90501

MAR 10 2008

Re: K073475
Trade/Device Name: System plus Impression Material
Regulation Number: 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: December 6, 2007
Received: December 18, 2007

Dear Ms. Chamberlain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073475

Device Name: System Plus Impression Material

Range of Indications:

System Plus is a vinyl polysiloxane dental impression material. It is ideal for one-step impressions to reproduce the structure of a patient's teeth and gums to produce crowns, bridges, inlays, partial and complete dentures, denture repairs, implants and other dental restorations prescribed by a dentist.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073475